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510(k) Summary

MAY 3 1 2006

Inspirstar Glove Electrode

1. Submitters Identification

a. Company Name:	Inspirstar Inc.
b. Company Address:	891 N. Naples Dr. Chandler, AZ 85226, USA
c. Contact Person:	Ning Wu, Vice President
d. Date of Summary Preparation:	April 15, 2006

2. Device Identification

a. Common Name:	Electrode, Cutaneous
b. Trade Name:	Inspirstar Glove Electrode
c. Classification:	Class II
d. Product Code:	GXY
e. Regulation Number:	882.1320

3. Device Description

Inspirstar Glove Electrode is the conductive glove knitted from a continuous silver coated nylon yarn into the form of the glove. The conductivity is derived from the silver material of nylon yarn. Nylon yarn provides elasticity which can ensure skin contact. Inspirstar Glove Electrode has the same conductivity for dry or wet usage. The entire glove electrode is conductive having the resistance of less than 7 ohms per inch consistently.

4. Intended Use

Inspirstar Glove Electrode is intended to for use with legally marketed electrostimulation devices such as TENS to deliver stimulation current for pain relief.

5. Legally Marketed Predicate Devices

Inspirstar Glove Electrode is substantially equivalent to the following predicate device. See Table 5-1 Predicate Device.

Table 5-1 Predicate Device

Device Name	Manufacturer	510(k) No.	Date Cleared
TheraKnit Garment Electrode	Neurotron Medical, Inc	K053214	12/20/2005

6. Substantial Equivalence Summary

Inspirstar Glove Electrode has the same indications for use as the legally marketed predicate device. Inspirstar Glove Electrode has same technological characteristics, the same conductivity performance, the similar connector interface and similar use and care characteristics as the predicate device. Overall, Inspirstar IS02 Microcurrent Stimulator is substantially equivalent to legally marketed predicate devices.

7. Technological Characteristics

Inspirstar Glove Electrode is knitted by traditional knitting process from a continuous silver coated nylon yarn into the form of the glove. The conductivity is derived from the silver material of nylon yarn. The resistance measurement on the glove is less than 7 ohms per inch. Inspirstar Glove Electrode can be used as one electrode, positive or negative polarity, on the current path of circuit. Another Inspirstar Glove Electrode or other electrode can be used as opposite polarity on the current path. Nylon yarn provides elasticity which can ensure skin contact.

8. Testing

Inspirstar Glove Electrode is tested to verify the device meets the design requirement. Predicate devices are also tested to support substantial equivalence.

9. Conclusions
Inspirstar Glove Electrode is substantial equivalent to legally marketed predicative devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2006

Inspirstar Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K061343
Trade/Device Name: Inspirstar Glove Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode,
Regulatory Class: Class II
Product Code: GXY
Dated: May 11, 2006
Received: May 15, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

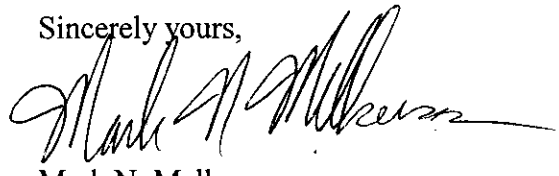
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061343

Device Name: Inspirstar Glove Electrode

Indications for Use:

Inspirstar Glove Electrode is cutaneous electrode to be used with legally marketed TENS stimulating device. The glove electrodes will deliver the stimulation signals generated by the stimulator to the skin with which they are contact.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061343